MUCUS RELIEF SEVERE CONGESTION AND COUGH MAXIMUM STRENGTH-dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid QUALITY CHOICE (Chain Drug Marketing Association)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purposes

Cough suppressant

Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep
 - nasal congestion due to a cold

Warnings

Do not use

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

When using this product,

do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough comes back, or occurs with fever rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in a 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL=milliliter
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: sodium 14 mg
- store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydate, xanthan gum

Principal Display Panel

*Compare to the active ingredients in Maximum Strength Mucinex® Fast-Max® Severe Congestion & Cough

Multi-Symptom Relief

Mucus Relief

Severe Congestion & Cough

Dextromethorphan HBr

Cough Suppressant

Guaifenesin

Chest Congestion & Mucus

Phenylephrine HCl

Stuffy Nose

For Ages 12+

Distributed by CDMA Inc©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Questions: 248-449-9300

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL IS BROKEN OR MISSING.

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Maximum Strength Severe Congestion & Cough.

Package Label



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PLD-B283C LB002418

Guaifenesin 400 mg.....Expectorant

Phenylephrine HCl 10 mg.....

PEEL CORNER FOR MORE DRUG FACTS

.....Nasal decongestant

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl

Drug Facts (continued)

gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

PEEL CORNER FOR MORE DRUG FACTS

Quality Choice Multi-Symptom Relief Mucus Relief

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-745
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL	

EDETATE DISODIUM (UNII: 7FLD91C86K) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 40 (UNII: WZB9127XOA) GLYCERIN (UNII: PDC6A3C0OX) PROPYL GALLATE (UNII: 8D4SNN7V92) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KOOR) SODIUM BENZOATE (UNII: OJ245FE5EU) TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) SORBITOL (UNII: 506T60A25R)	Inactive Ingredients		
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SORBITOL (UNII: 506T60A25R)	SODIUM BENZOATE (UNII: OJ245FE5EU)		
	TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
	SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)	SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)	XANTHAN GUM (UNII: TTV12P4NEE)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63868-745- 06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/3 1/2 0 15	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	0 1/3 1/2 0 15	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2019